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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,660	05/30/2007	Hoon Sunwoo	55326.15	2411

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EXAMINER
WEN, SHARON X

ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
11/09/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/599,660	SUNWOO ET AL.	
	Examiner	Art Unit	
	SHARON WEN	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-9 and 14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-9 and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after Final Rejection. Since this application is eligible for continued Examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/02/2009 has been entered.

2. Applicant's amendment, filed 09/02/2009, has been entered.

Claims 2 and 10-13 have been canceled.

Claim 14 has been added.

Claims 1, 3-9 and 14 are pending and currently under examination as they read on a therapeutic composition comprising anti-gluten egg yolk antibodies wherein the specific anti-gluten antibody reads on the elected anti-gliadin antibody.

3. This Action will be in response to Applicant's Arguments/Remarks, filed 09/02/2009.

The rejections of record can be found in the previous Office Actions, mailed 08/13/2008 and 03/02/2009.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1, 3-9 and 14 stand rejected under 35 U.S.C. 103 (a) as being unpatentable over Ellis et al. (*Gut* 1998, 43:190-195, reference of record) in view of Lee (U.S. Patent 5,367,054, reference of record).

Applicant's argument as well as the 132 Declaration have been considered in full but have not been found convincing essentially for reasons of record and reiterated herein for Applicant's convenience.

The present claims are drawn to a composition comprising anti-gluten IgY antibodies. Ellis et al. teach anti-gluten antibodies that are raised against gliadin, the elected species of anti-gluten antibody, wherein the antibodies are polyclonal and monoclonal IgG antibodies (see entire document, in particular, see page 190, last paragraph on the right column).

The difference between the teaching of Ellis and the present claims is that Ellis's antibodies are not IgY antibodies. However, raising IgY antibodies was a well-known technology in the art at the time of the invention was made as evidenced by Lee (see entire document, in particular, see Background of the Invention). In particular, Lee teaches the process of producing egg yolk antibodies by 1) immunizing the egg-laying fowl with the antigen of interest; 2) collect eggs from the immunized fowl; and 3) prepare the composition from the egg yolk or IgY purified from the egg yolk (see e.g., column 8, lines 7-15, and Figure 1). Moreover, Lee teaches the egg yolk is liquid or dried in the purification process (see Figure 1 and column 3, lines 51-57).

Given that Ellis et al. teach using the anti-gliadin antibody containing composition for immunodetection and the teaching by Lee on the advantage of making IgY antibodies i.e., that egg yolk is a very good source of specific antibodies and that the antibodies are more specific (see column 1, lines 34-46), one of ordinary skill in the art would have been motivated to make the anti-gliadin antibodies for immunodetection as IgY antibodies for the high specificity offered by the egg yolk.

Moreover, ordinary skill in the art would have reasonable expectation of success in making the anti-gliadin IgY antibodies in view of the detailed procedures in making and purifying IgY antibodies outlines in Lee (see e.g., column 8, lines 7-15, and Figure 1) and the detailed disclosure of how to prepared the gliadin antigen taught by Ellis et al. (see page 191, left column).

In view of the composition comprising the anti-gluten antibodies taught by Ellis et al. (see paragraph bridging pages 191-192) and the advantage and practicality in IgY production taught by Lee (see Background of the Invention and Figure 1), it would have been *prima facie* obviate to make an anti-gluten IgY antibody.

Regarding the product-by-process limitation for producing the antibody provided by the present claims, is noted that such process does not distinguish from the antibody in the art.

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Furthermore, it is noted that the claims provide intended uses for the composition comprising the antibody (i.e., for treating celiac disease and for oral administration) but such intended uses do not distinguish from the composition in the art. See e.g. MPEP § 2114.

In contrast to Applicant's assertion that Ellis teaches away from the use of polyclonal anti-gliadin IgG antibodies, the following is noted:

A prior art reference may be considered to teach away when "a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." See In re Gurley , 31 USPQ2d 1130, 1131 (Fed. Cir. 1994).

Here in contrast to Applicant's assertion of teaching away by Ellis because the prior art discussed that polyclonal antibody based assays in general lack specificity; there is no discouragement nor skepticism in the prior art for generating polyclonal anti-gliadin IgG antibodies, particularly in light of the prior art teachings in using polyclonal anti-gliadin IgG antibodies as a capture antibody in the ELISA assay.

Under the broadest reasonable interpretation, the present claims read on an anti-gliadin IgY polyclonal antibody. The claims do **not** specify any level of the antibody binding to gliadin, thus the claims read on any measurable gliadin-binding. Given that Ellis taught raising a polyclonal IgG antibody against gliadin and using the polyclonal antibody in the gliadin detection assay, the prior art taught by Ellis is not deemed deficient nor teaching away.

Moreover, in response to Applicant's argument that Ellis did not teach or suggest the direct administration of antibodies to immunize a subject so as to inhibit the transport of gluten into the mucosal membrane, it is noted that such limitation is an intended use for the composition comprising the antibody (i.e., for treating celiac

disease and for oral administration) but such intended uses do not distinguish from the composition in the art. See e.g. MPEP § 2114.

Furthermore, in response to Applicant's characterization of Examiner's position on using Lee as the primary reference, it is noted that the first line of the rejection in the previous Office Actions inadvertently stated Lee over Ellis. However, the grounds of rejection of record have been clearly and consistently set forth based on Ellis as the primary reference, i.e., given that Ellis taught an IgG polyclonal antibody against gliadin, it would have been obvious to make an IgY polyclonal antibody against gliadin in view of the well-known IgY technology and advantages of IgY taught by Lee. Examiner apologizes for the confusion on this matter. However, the grounds of rejection have not been changed.

The rationale to support a conclusion that the claims would have been obvious is that all the claimed elements (e.g., anti-gluten antibody / IgY antibodies) were known in the prior art and one skilled in the art could have arrived at the claimed invention by using known methods (making an anti-gluten antibody and making an IgY antibody) with no change in their respective functions and the combination would have yielded nothing more than predictable results of making an anti-gluten IgY antibody.

The rationale to support a conclusion that the claims would have been obvious is that a particular known technique (making IgY antibodies) was recognized as part of the ordinary capabilities of one skilled in the art. One of ordinary skill in the art would have been capable of applying this known technique to a known product (e.g. anti-gluten antibody) that was ready for improvement and the results would have been predictable to one of ordinary skill in the art.

Given that antibodies were well-known in the art for their pharmaceutical and therapeutic uses, it would have been obvious to one of ordinary skill in the art, at the time of the invention was made to make an composition comprising an anti-gluten IgY antibody for pharmaceutical or therapeutic purposes because IgY antibodies were known to offer advantages over the conventional antibodies as taught by Lee (see, e.g., column 1, lines 35-47). In particular, IgY antibodies are relatively easy to produce and have high specificity. Moreover, IgY antibodies provide oral routes of administration.

Therefore, one of ordinary skill would have been motivated to make an anti-gluten IgY antibody given the advantages of IgY antibodies over the conventional antibodies.

Furthermore, it would have been obvious to one of ordinary skill in the art to include a physiologically acceptable carrier, excipient or diluent, which reads on water or any physiological buffer.

Once a prima facie case of obviousness has been made the burden of going further is shifted to applicant. In re Keller, 642 F.2d 4B, 208 USPQ 871, 882 (CCPA 1981). This applicant has not done, but rather argues the references individually and not their combination. One cannot show non-obviousness by attacking references individually where the rejections are based on a combination of references. In re Young 403 F.2d 759, 150 USPQ 725 (CCPA 1968). See MPEP 2145.

In response to the newly added limitation, "wherein the IgY polyclonal antibodies upon oral administration to the subject inhibit transport of gliadin into the mucosal membrane of the gastrointestinal tract of the subject", it is noted that the wherein clause is a functional characterization of the antibody but does not add any structure to the antibody. Products of identical chemical composition cannot have mutually exclusive properties. Given that the teachings by Ellis in view of Lee have rendered obvious of the IgY polyclonal anti-gliadin antibody, one of ordinary skill in the art would have recognized that the same or nearly the same antibody would necessarily have the recited function. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01.

Applicant's arguments have not been persuasive.

Therefore, the rejection of record is maintained for the reasons of record, as it applies to the amended claims.

Conclusion

6. No claim is allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHARON WEN whose telephone number is (571)270-3064. The examiner can normally be reached on Monday-Thursday, 8:30AM-6:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571)272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sharon Wen/
Examiner, Art Unit 1644
November 3, 2009

/Phillip Gambel/
Primary Examiner
Technology Center 1600
Art Unit 1644
November 5, 2009